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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/229,229	01/12/1999	GEOFFREY M. WAHL		7340

7590

11/05/2002

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EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 11/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/229,229

Applicant(s)

WAHL ET AL.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-27 and 31-54 is/are pending in the application.
- 4a) Of the above claim(s) 5-27, 31, 32, 51 and 52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-50, 53 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 26. 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election of Group I, claims 33-50, 53 and 54, in Paper No. 28, filed 7/30/2002, is acknowledged. Applicant elected with traverse on the grounds that examination of the two groups would not place an undue burden on the examiner. This is not found persuasive because the inventions of the two groups are classified differently, and because the scope of group II is extremely broad. This restriction requirement is proper and is maintained and is made final.

2. Claims 51 and 52 were canceled.

Claims 5-27, 31-50, 53 and 54 are pending.

Claims 5-27, 31, and 32, drawn to non-elected inventions, are withdrawn from consideration.

Claims 33-50, 53 and 54 are examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 33-36, 39-50, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiraoka (Nature (1989) 342: 293-296) in view of Abken (Cancer Journal (1995) 8(3): 94-102).

Claims 33-36, 39-46, 48-50, 53 and 54 are drawn to methods to identify an agent that increases or decreases the amount of double minute chromosomes or extrachromosomal DNA in a cells comprising contacting the cell with the agent, wherein the cel expresses a labeled protein that associates with double minute chromosomes or extracellular DNA to form a labeled complex and comparing the amount of the labeled complex contained in the cell contacted with

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the agent with the amount of labeled complex contained in a cell that was not contacted with the agent.

Hiraoka teaches a method for visualizing chromosomes in drosophila by imaging chromatin that had assembled fluorescent-labeled histones , H2A or H2B conjugated with rhodamine.

Abken teaches that extrachromosomal DNA and double minute DNA is chromosomal in origin and that double minute DNA can be eliminated from cancer cells by micronuclei formation in response to administration of various drugs. Abken also teaches that extrachromosomal DNA such as double minute DNA contains extra copies of oncogenes, which may cause the growth dysregulation of cancer cells.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art to use the technique of chromosome visualization taught by Hiraoka to make a method for identifying other agents that induce micronuclei formation and thereby decrease the amount of double minute chromosomes. Alternatively, because the presence of double minutes is associated with carcinogenesis, it would be prima facie obvious to use the technique of Hiraoka to identify agents that increase the amount of double minute DNA or extrachromosomal DNA.

4. Claims 33-38, 42-50, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinett (Journal of Cell Biology (1996) 135(6): 1685-1700) in view of Abken (Cancer Journal (1995) 8(3): 94-102).

Claims 33-38, 42-50, 53 and 54 are drawn to methods to identify an agent that increases or decreases the amount of double minute chromosomes or extrachromosomal DNA in a cells comprising contacting the cell with the agent, wherein the cell expresses a labeled protein that associates with double minute chromosomes or extracellular DNA to form a labeled complex and comparing the amount of the labeled complex contained in the cell contacted with the agent with the amount of labeled complex contained in a cell that was not contacted with the agent. The labeled protein may be fluorescent protein fused to a protein that associates with DNA, where the fluorescent protein is Aequorea victoria green fluorescent protein.

Robinett teaches a method for visualizing chromosomes in Chinese Hamster Ovary (CHO) cells by transfecting cells with an expression vector containing DNA encoding a GFP-lac repressor-nuclear localization signal fusion protein (page 1687).

Abken teaches that extrachromosomal DNA and double minute DNA is chromosomal in origin and that double minute DNA can be eliminated from cancer cells by micronuclei formation in response to administration of various drugs. Abken also teaches that extrachromosomal DNA such as double minute DNA contains extra copies of oncogenes, which may cause the growth dysregulation of cancer cells.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art to use the technique of chromosome visualization taught by Robinett to make a method for identifying other agents that induce micronuclei formation and thereby decrease the amount of double minute chromosomes. Alternatively, because the presence of double minutes is associated with carcinogenesis, it would be prima facie obvious to use the technique of Robinett to identify agents that increase the amount of double minute DNA or extrachromosomal DNA.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
November 4, 2002

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